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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/541,671

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Takashi Nakamura

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EXAMINER

WALKER, AMANDA H

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/541,671	<b>Applicant(s)</b> NAKAMURA ET AL.	
	<b>Examiner</b> AMANDA H. WALKER	<b>Art Unit</b> 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11-29-07.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 November 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawatani et al. (JP 5-56990 A) in view of Kokubo (United States Patent Number 5,609,633). All references to Kawatani et al. are to the English translation provided in the previous Office Action.

Regarding Claims 1, 2, 3, 7, 8, 9, and 11: Kawatani et al. teaches a porous rough film/body comprising a lump of titanium or titanium alloy (para. 13) and having a porosity of 40-60% (Fig. 1). The body has a larger pore interconnected in a three-dimensional network with a diameter of 100 to 200 micrometers and smaller holes with diameters of 50 microns or (para. 0003). The porous network penetrates the rough film/body from one end to the other. Considering the varied diameters of the pores in Kawatani et al., it is inevitable that the claimed structure (a smaller hole on an inner surface of the larger interconnected pore) would appear. The range of the pore taught by Kawatani et al. (100-200 micrometers) anticipates the range in claim 11 (MPEP 2131.03 II). However, Kawatani et al. does not teach the film comprising at least one phase selected from the group consisting of an amorphous titanium oxide phase, an amorphous alkali titanate phase, an anatase phase and a rutile phase aligned with (101) plane.

Kokubo teaches the film comprising at least one phase selected from the group consisting of an amorphous titanium oxide phase, an amorphous alkali titanate phase, an anatase phase and a rutile phase aligned with (101) plane (2:4-13 and Table 1). Kokubo also teaches that the desirable thickness of the film comprising at least one phase selected from the group consisting of an amorphous titanium oxide phase, an amorphous alkali titanate phase, an anatase phase and a rutile phase aligned with (101) plane is 0.1 to 10 micrometers (2:25-26). This film is made by immersing the titanium in an alkaline aqueous solution followed by a heat treatment (2:30-35). The heat treatment temperature is anywhere from 300 to 800 degrees C (2:40-45). The implant is washed in distilled water after the immersion and before the heat treatment (4:20-25). Kawatani et al. and Kokubo are combinable because they are from the same field of endeavor, namely, bone implants. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have modified the porous endosseous implant of Kawatani et al. with the osteoinductive film/layer taught by Kokubo, and one would have been motivated to do so because Kokubo suggests that a substrate covered by a film including a phase of alkali titanate would induce the growth of apatite thereon (3:18-24), thus increasing the ability to bond with the bones of the body (1:15-19).

Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawatani et al. (JP 5-56990 A) in view of Kokubo (United States Patent Number 5,609,633) as applied to claim 3 above, and further in view of Johnson et al. (United States Patent Application Number 2001/0053937). All references to Kawatani et al. are to the English translation provided in the previous Office Action.

Regarding Claims 4-6: Kawatani et al. teaches the plasma sprayed body/rough film as applied above. The body is formed by plasma spraying small, irregular titanium particles to a

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base material/plate (para. 0009). The substrate/base material taught by Kawatani et al. could be considered a "plate". Furthermore, the titanium powder of Kawatani et al. comprises a group of irregular particles and each of the particles is porous. The porous particles are irregular by nature, considering that: 1. the particles are of varying sizes and 2. the voids are not identical in every particle. Finally, the titanium powder comprises a fine powder having a particle diameter having a particle diameter of 20-30 microns and a coarse/titanium sponge powder having a particle diameter of 100-300 microns (para. 13) (See MPEP 2131.03 and 2144.05). However, Kawatani et al. does not specifically teach a method of shaping this article.

The action of cutting the plasma sprayed metal after it has been plasma sprayed does not merit patentability because it common in the art to cut porous metal materials in order to shape them for implantation. For example, Johnson et al. teaches a porous titanium (para. 0032) bone substitute material that can be shaped by machining/cutting (para. 0048). At the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the plasma sprayed body taught by Kawatani et al. by the shaping/machining/cutting process taught by Johnson et al., and one would have been motivated to do so in order to be sure that the implant would fit the orthopedic region in question.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawatani et al. (JP 5-56990 A) in view of Larsson et al. (United States Patent Number 6,689,170). All references to Kawatani et al. are to the English translation provided in the previous Office Action.

Kawatani et al. teaches a porous rough film/body comprising a lump of titanium or titanium alloy (para. 13) and having a porosity of 40-60% (Fig. 1). The body has a larger pore set interconnected in a three-dimensional network with a diameter of 100 to 200 micrometers

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and smaller holes with diameters of 50 microns or less (para. 0003). The porous network penetrates the rough film/body from one end to the other. Considering the varied diameters of the pores in Kawatani et al., it is inevitable that the claimed structure (a smaller hole on an inner surface of the larger interconnected pore) would appear. However, Kawatani et al. does not anodizing the body in an electrolytic solution.

Larrson et al. teaches an implant for permanent anchorage in bone tissue which is made of titanium with a titanium oxide surface which has been modified by anodization (Abstract). Kawatani et al. and Larrson et al. are combinable because they are from the same field of endeavor, namely, bone implants. It would have been obvious to a person having ordinary skill in the art at the time of the invention to have combined the method of anodizing the body/implant in an electrolytic solution taught by Larrson et al. with the porous body/implant component taught by KAWATANI ET AL., and one would be motivated to do so because anodization increases the oxide thickness on the titanium surface, and titanium oxide is suspected to increase the biocompatibility of titanium due to the polarity of its surface. The polarity attracts calcium ions and helps to incorporate calcium into the surface (2: 18-19, 3:36-40, 7:25-28, 10: 4-6).

### ***Response to Arguments***

Applicant's arguments filed 12-14-07 have been fully considered but they are not persuasive.

In regards to claims 1-2 and 3-9, Applicant argues that the porous "rough film" taught by Kawatani et al. does not anticipate the "porous body" of the instant claim because the pore of Kawatani et al. does not penetrate the base material. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features

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upon which applicant relies (i.e., pores that penetrate the entire implant) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). While the Examiner agrees that the pores of Kawatani et al. do not penetrate the base material, this was not a limitation of the original instant claim, and is thus irrelevant. The broadest reasonable interpretation of the claim does not require that the pores on the outer surface of the implant would penetrate its entire volume, and thus the “rough film” taught by Kawatani et al. could in itself be considered a “porous body”.

Also in regards to claims 1 and 2, Applicant argues that neither Kawatani et al. nor Kokubo teach the property of osteoinductivity, but only bioactivity. In the originally filed disclosure, the Applicant states “it has been known that specific ceramic porous bodies comprising hydroxyl apatite etc. has osteoinductivity, which can induce bone formation even in a location which a bone does not intrinsically exist” (page 2, lines 4-10). The Examiner holds that the combination (the film taught by Kokubo on the porous body taught by Kawatani et al.) would inherently be osteoinductive. The film taught by Kokubo has the ability to “bond with bones” (1:25-30) because a layer of apatite is formed on its surface. The reason that the ceramic mentioned in Applicants disclosure (page 2, lines 4-10) is osteoinductive is also the layer of apatite. Paired with the porous body taught by Kawatani et al., the combination appears to have the necessary properties (porosity and a layer of apatite) to induce bone formation anywhere in the body and thus be “osteoinductive”. The osteoinductivity would be an inherent result of coating the pores in apatite.

Applicant requests clarification to the Examiner’s assumption that the larger “pore” in the porous body/rough film taught by Kawatani et al. would inevitably have smaller “holes” on its inner surface (Remarks, p. 11, third paragraph). Kawatani et al. explains that the plasma spray

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process (spraying tiny, variously sized titanium particles) creates pores of various sizes. Some of these sizes are less than 50 micrometers, while others are larger (100-200 micrometers) (Kawatani et al. translation, para. 0003). Since all of these variously sized pores are connected, at some point a smaller pore (hole) will intersect a larger one (pore), thus creating a (smaller) hole on the inner surface of the (larger) pore.

Applicant's arguments with respect to claims 4-6 rely on a newly added amendment.

Applicant's arguments with respect to Claims 7-10 rely on their argument that the "rough film" does not anticipate the "porous body" of the instant claim, which was addressed on the previous page.

Applicant's arguments with respect to the obviousness-type double patenting rejection are found persuasive and the rejection has been withdrawn.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA H. WALKER whose telephone number is (571)270-3296. The examiner can normally be reached on 8-5, M-Th, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

AHW  
2-15-08